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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/746,919	12/22/2000	Howard Marcellus Johnson	5600-0001.37	2742

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EXAMINER	
SEHARASEYON, JEGATHEESAN	

ART UNIT	PAPER NUMBER
1647	18

DATE MAILED: 06/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/746,919	JOHNSON ET AL.	
	Examiner	Art Unit	
	Jegatheesan Seharaseyon	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 March 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *66-71 and 97* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *66-71 and 97* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. This office action is response to the amendment filed 3/27/03 in Paper No: 17. Claims 66-71 and 97 are pending.

Specification

2. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. "Ovine interferon tau composition and use thereof to inhibit viral replication" is suggested.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

63a. Claims 66-71 and 97 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, but whether, if experimentation is necessary, it is undue. See *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404. The test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue. The factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary

experimentation is "undue" include, but are not limited to: (1) the breadth of the claims; (2) the nature of the invention; (3) the state of the prior art; (4) the level of one of ordinary skill; (5) the level of predictability in the art; (6) the amount of direction provided by the inventor; (7) the existence of working examples; and (8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The specification is insufficient to enable one skilled in the art to practice the claimed invention without an undue amount of experimentation. Applicant has shown data for Peripheral blood mononuclear cells (PBMC) infected with HIV, and HepG2-T14 infected with Hepatitis B, followed by ovine interferon-τ treatment (pages 98-101). The prior art does not disclose that the above-mentioned tissue culture methods are acceptable models for *in vivo* treatment. The therapeutic effect of ovine interferon-τ therapy can be species and model-dependent. In addition, there is no evidence indicating that the disclosed human PBMC or HepG2-T14 cell assay of ovine interferon-τ is an art recognized model to study the anti-viral effect of the ovine interferon-τ (Example 18). *In vitro,* studies often to do not correlate well or predict the *In vivo*, effect of the cytokines. Furthermore, there is no indication that the assay accurately reflects the effect of ovine interferon-τ in the dynamic environment of a living subject.

Although, Applicant described ovine interferon-τ doses to inhibit in cells, there is no guidance provided in choosing the therapeutically effective amount for administering to the subjects to treat the various viral replications (infections) contemplated in the instant invention. There is insufficient evidence of the invention with respect to the *in*

vivo operability of the claimed invention because the specification lacks working examples. Applicant has not disclosed how to use the claimed invention to treat the viral infections caused by the infection of HIV and Hepatitis B virus on the subjects (pages 98-101). The languages of the claims are not strictly limited to *in vitro* treatments and encompass treating patients with viral infections and as such do not have support in the specification. There is insufficient disclosure to reasonably predict that the methods of the instant specification could be used to treat infection by inhibiting replication of the virus *in vivo*. In addition, it is unclear if the same dose indicated will be sufficient for inhibiting both HIV and Hepatitis B viral infection.

Applicant has shown data for Peripheral blood mononuclear cells (PBMC) infected with HIV, and HepG2-T14 infected with Hepatitis B, followed by ovine interferon-τ treatment (pages 98-101), without treating affected subjects or shown an art recognized correlation between the data shown and the scope of the claimed invention. The artisan would recognize and appreciate that there is often no known correlation between *in vitro* and *in vivo* results, because the artisan recognizes that an *in vitro* assay cannot duplicate the complex conditions of *in vivo* treatment. For example, in the *in vitro* assay, the ovine interferon-τ is in contact with cells during the entire exposure period. This is not the case *in vivo* where exposure to the target cells (site) may be delayed or inadequate. In addition, variables such as biological stability, half-life, or clearance from the blood are important parameters in achieving successful therapy. Pharmaceutical therapies are unpredictable for the following reasons; (1) the proteins may be inactivated before producing an effect, i.e. such as proteolytic degradation,

immunological inactivation or due to an inherently short half life protein; (2) the protein may otherwise not reach the target area because, for example, the protein may not be able to cross the mucosa; (3) other functional properties, known or unknown, may make the protein unsuitable for *in vivo use*, i.e. may produce adverse side effects prohibitive to the use of such treatment; (4) the in vivo environment is complex, and not limited to the single cell type used in the assay.

Since applicant has not provided any working examples of the efficacy of using ovine interferon-τ in treating already established disease subjects viral infection, it would require an undue amount of experimentation to one of skill in the art to practice the claimed invention. There are no specific teachings in the disclosure that would allow one to have a reasonable expectation of success in transferring the *in vitro* method to treat viral infections. One is only left with speculation and an invitation to experiment.

Given the breadth of claims 66-71 and 97, in light of the unpredictability of the art as determined by the lack of working examples, the level of skill of the artisan, and the lack of guidance provided in the instant specification and the prior art of record, it would require undue experimentation for one of ordinary skill in the art to make and use the claimed invention of inhibiting all viral infections. In addition, due to the lack of established protocols for effective inhibition viral replication using ovine interferon-τ, undue experimentation would be required to practice the claimed invention and would have little expectation of success.

3b. Claim 67 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for inhibiting HIV virus replication does not reasonably provide

enablement for inhibiting Hepatitis C viral replication. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Although, Applicant has shown inhibition of viral replication for HIV (a RNA virus) and Hepatitis B (a DNA virus) using ovine interferon-τ the specification but fails to provide any guidance regarding the inhibition Hepatitis C virus (pages 98-101). There are no working examples to indicate that interferon-τ would indeed inhibit the replication of Hepatitis C infection. In addition, there is no guidance provided in choosing the amount of interferon-τ needed to inhibit Hepatitis C viral replication without increasing the affecting the toxicity in both *in vitro* and *in vivo*. It is also not clear what cells need to be used for testing the efficacy of inhibition. Thus, undue amount of experimentation would be required to establish if ovine interferon-τ would inhibit the viral replication of Hepatitis C.

Applicants have not taught how one of skill in the art would use the full scope of inhibiting both HIV virus and Hepatitis C virus encompassed by the invention of claim 67. The amount of experimentation required to make and/or use the full scope of the claimed method would require trial and error experimentation to determine the cell lines, amount of interferon to be used. Given the breadth of claim 67 in light of the unpredictability of the art as determined by the lack of working examples and shown by the prior at of record, the level of skill of the artisan, and the lack of guidance provided in the instant specification, it would require undue experimentation for one of ordinary skill in the art to use the claimed invention.

4. No claims are allowable.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jegatheesan Seharaseyon whose telephone number is 703-305-1112. The examiner can normally be reached on M-F: 8:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 703-308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-0294 for regular communications and 703-308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Gary L Kunz

GARY KUNZ
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JS
June 14, 2003